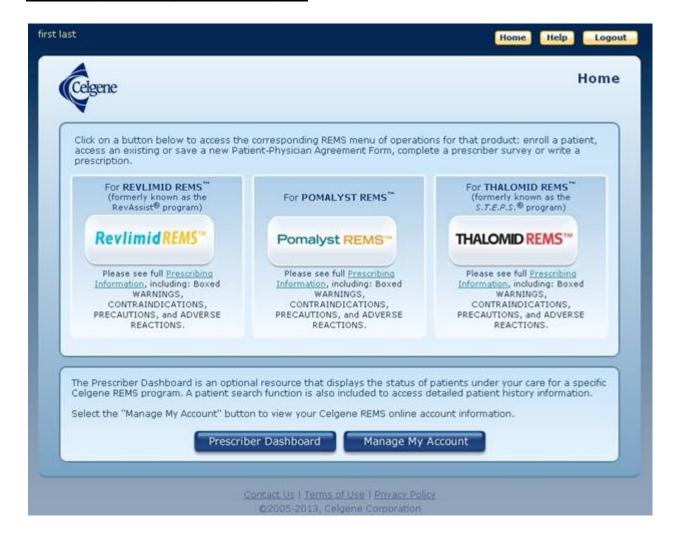
CelgeneRiskManagement.com

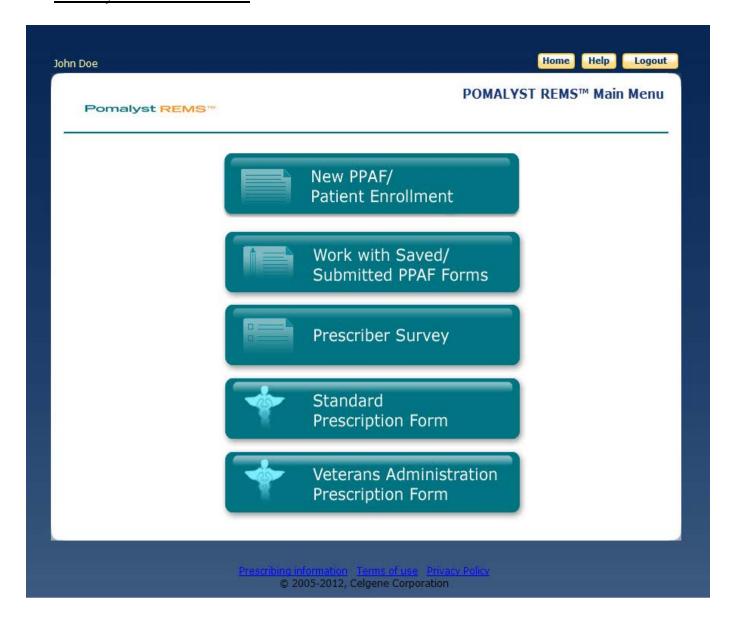
Login Page



Home Page (after prescriber logon)



Pomalyst REMS module



www.POMALYSTREMS.com Web site



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Pomalyst REMS™



For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

About the POMALYST REMS™ program

POMALYST® (pomalidomide), in combination with dexamethasone, is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

To avoid embryo-fetal exposure, POMALYST is only available under a restricted distribution program called "POMALYST Risk Evaluation and Mitigation Strategy (REMS)™." Only certified prescribers can prescribe POMALYST and only certified pharmacles can dispense POMALYST in the POMALYST REMS™ program.

In order to receive POMALYST, all patients must be enrolled in POMALYST REMS™ and agree to comply with the requirements of the POMALYST REMS™ program.

Key points of the POMALYST REMS™ program

- The prescriber enrolls and becomes certified with Ceigene for the POMALYST REMS™ program
- . The prescriber counsels patient on benefits and risks of POMALYST
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a POMALYST® (pomalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- . The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends POMALYST prescription to a certified pharmacy

- The pharmacy certifies with Celgene for POMALYST REMS™ program
 The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy counsels the patient, and completes an Education and Counseling Checklist
- The certified pharmacy dispenses POMALYST to patient along with a Medication Guide

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Pomalyst REMS™



Prescriber Resources

POMALYST® (pomalidomide), in combination with dexamethasone, is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

Enrolling in POMALYST REMS™

In order to prescribe POMALYST, you must enroll in the POMALYST REMS™ program and agree to follow the requirements of the program. You can enroll by visiting ColgeneRiskManagement.com, a website that allows prescribers to handle the REMS process for all of the Celgene REMS programs. You can also download the Prescriber Enrollment Form below and fax it to Celgene Customer Care at 1-888-432-9325.



Full Prescribing Information

REPORTING TO CELGENE

Fax:

Prescribing POMALYST for your patients

In order to receive POMALYST, your patients must also be enrolled in the POMALYST REMS[™] program. You can enroll your patients, and fill out a prescription form using CelgeneRiskManagement.com. You and your patients can also complete your mandatory confidential surveys there.

Additionally, you can also enroll your patients and write prescriptions by downloading the Desktop Software and installing it on your computer.



Please report adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST to Celgene using any of the following methods:

Email:	drugsafety@celgene.com
Telephone:	1-908-673-9667
Toll-free:	1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Care Center)
Fax:	1-908-673-9115
Mall to:	Global Drug Safety & Risk Management Celgene Corporation 300 Connell Dr. Suite 6000 Berkeley Heights, NJ 07922
REPORTING TO	THE FDA
suspected pregn	periences that are suspected to be associated with the use of POMALYST and any ancy occurring during the treatment with POMALYST may also be reported to the FDA riting System using any of the following methods:
Online:	https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
Telephone:	1-800-FDA-1088

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1-800-FDA-0178

5600 Fishers Lane Rockville, MD 20852-9787





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1-800-FDA-0178

MedWatch 5600 Fishers Lane Rockville, MD 20852-9787

Online:

Fax:

Mail to:

Telephone: 1-800-FDA-1088

Adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST may also be reported to the FDA MedWatch Reporting System using any of the following methods:

https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm

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